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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/632,121  | 07/31/2003  | Kathleen E. Briscoe  | 1023-118US01        | 1849             |
| 28863   | 7590        | 02/09/2006           | EXAMINER            |                  |
| SHUMAKER & SIEFFERT, P. A.<br>8425 SEASONS PARKWAY<br>SUITE 105<br>ST. PAUL, MN 55125 |             |                      | WILLIAMS, KENNETH C |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3739                |                  |

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/632,121

Applicant(s)

BRISCOE ET AL.

Examiner

Kenneth C. Williams

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/28/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Amendment*

1. In response to the amendment filed on November 28, 2005, claims 1-3, 5, 9, 12, 14-17, 21, 26-31, 33, 34, 37-39 and 41 *stand* rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,416,480 to Nenov. Claims 4, 18 and 32 *stand* rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,480 to Nenov in view of U.S. Patent No. 6,406,427 to Williams et al. Claim 6 *stands* rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,480 to Nenov in view of U.S. Patent No. 6,887,199 to Bridger et al. Claims 7, 8, 13, 19, 22 and 25 *stand* rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,480 to Nenov in view of U.S. Patent No. 5,486,204 to Clifton. Claims 10, 11, 20 and 36 *stand* rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,480 to Nenov in view of U.S. Patent Application No. 2002/0004729 to Zak et al. Claims 23 and 24 *stand* rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,480 to Nenov in view of U.S. Patent No. 5,486,204 to Clifton, and further in view of U.S. Patent No. 6,277,143 to Klatz et al. Claims 35 and 40 *stand* rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,480 to Nenov in view of U.S. Patent No. 6,277,143 to Klatz et al.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3739

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5, 9, 12, 14-17, 21, 26-31, 33, 34, 37-39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Nenov (U.S. Patent No. 6416480).

**In regards to Claim 1**, Nenov discloses a method comprising "receiving data concerning a patient" (See Figure 2, elements 24 and 28; see also see column 8, line 62 – column 9, line 4) and "selecting a brain injury protocol as a function of the data" (See column 1, lines 13-20).

**In regards to Claim 2**, Nenov discloses a method comprising "receiving the data from an operator" (See column 9, lines 60-64).

**In regards to Claim 3**, Nenov discloses a method comprising "receiving the data from a monitoring device" (See Figure 3B, elements 24, 28 and 42; also see column 10, lines 30-32).

**In regards to Claim 5**, Nenov discloses a method comprising "the data comprise at least one of a physical condition of the patient, a mental condition of the patient and a complaint from the patient" (See column 3, lines 53-56).

**In regards to Claim 9**, Nenov discloses a method comprising "presenting an operator with a task to be performed pursuant to the brain injury protocol; and receiving an acknowledgement from the operator that the task has been performed" (See Figure 2, elements 22, 24, 26 and 28).

**In regards to Claim 12**, Nenov discloses a method comprising "presenting a checklist to an operator pursuant to the brain injury protocol, the checklist requesting

entry of additional data concerning the patient; and receiving the additional data from the operator (See column 17, lines 51-64).

**In regards to Claims 14 and 17**, Nenov discloses a method comprising “further comprising determining a presumptive diagnosis as a function of the data” (See Figures 5A-5D; also see column 1, lines 13-20 and column 17, lines 9-50).

**In regards to Claim 15**, Nenov discloses a method comprising “presenting a checklist to an operator, the checklist requesting entry of data concerning a neurological condition of a patient” (See column 17, lines 51-64), “receiving the data from the operator” (See column 9, lines 60-64), “receiving additional data concerning the patient from a monitoring device” (See Figure 3B, elements 24, 28 and 42; also see column 10, lines 30-32), and “selecting a brain injury protocol as a function of the data” (See column 1, lines 13-20).

**In regards to Claim 16**, Nenov discloses a method comprising “the checklist comprises at least one of a Cincinnati Prehospital Stroke Scale, a Los Angeles Prehospital Stroke Screen, a Glasgow Coma Scale and a Hunt and Hess Scale for Subarachnoid Hemorrhage” (See column 1, lines 13-20).

**In regards to Claim 21**, Nenov discloses a system comprising “a monitoring device to monitor a medical condition of a patient and to generate data concerning the patient” (See Figure 2; also see column 10, line 66-column 11, line 5) and “a processor to receive the data from the monitoring device and to select a brain injury protocol as a function of the data” (See Figure 2, element 18; also see column 9, lines 5-21).

**In regards to Claim 26**, Nenov discloses a system comprising “an input device to receive additional data concerning the patient from an operator” (See Figure 2, see also column 8, line 62 – column 9, line 4).

**In regards to Claim 27**, Nenov discloses a system comprising “the input device comprises at least one of a button, a keyboard, a touch screen, a voice recognition module and a pointing tool” (See Figure 2, element 14).

**In regards to Claim 28**, Nenov discloses a system comprising “an output device to present brain information pursuant to the brain injury protocol” (See Figure 2, element 16; see also column 8, lines 65-67).

**In regards to Claim 29**, Nenov discloses a system comprising “the output device comprises at least one of a touch screen, a display screen, an audible sound generator, a voice synthesizer, a printer and an indicator light” (See Figure 2, element 16; see also column 8, lines 65-67).

**In regards to Claim 30**, Nenov discloses a system comprising “memory to store at least one of a brain injury protocol and a datum concerning the patient” (See column 6, lines 15-18).

**In regards to Claim 31**, Nenov discloses a system comprising “a communication module to transmit data stored in the memory to a remote unit” (See Figure 3B; also see column 9, lines 22-33).

**In regards to Claim 33**, Nenov discloses a computer-readable medium comprising “instructions for causing a programmable processor to: receive data

concerning a patient; and select a brain injury protocol as a function of the data" (See column 22, line 60 – column 23, line 11).

**In regards to Claim 34**, Nenov discloses a computer-readable medium comprising "the instructions causing the processor to receiving the data from at least one of an operator and a monitoring device" (See column 22, line 60 – column 23, line 11).

**In regards to Claims 37 and 41**, Nenov discloses a computer-readable medium comprising "instructions causing the processor to determine a presumptive diagnosis as a function of the data" (See column 17, lines 9-50 and column 22, line 60 – column 23, line 11).

**In regards to Claim 38**, Nenov discloses a computer-readable medium comprising "instructions for causing a programmable processor to: present a checklist to an operator, the checklist requesting entry of data concerning a neurological condition of a patient; receive the data from the operator; receive additional data concerning the patient from a monitoring device; and select a brain injury protocol as a function of the data" (See column 15, lines 24-39 and column 22, line 60 – column 23, line 11).

**In regards to Claim 39**, Nenov discloses a computer-readable medium comprising "the checklist comprises at least one of a Cincinnati Prehospital Stroke Scale, a Los Angeles Prehospital Strike Screen, a Glasgow Coma Scale and a Hunt and Hess Scale for Subarachnoid Hemorrhage" (See column 22, line 60 – column 23, line 11).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4,18 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Williams et al. (U.S. Patent No. 6406427).

**In regards to Claims 4 and 18**, Nenov discloses a method using EMG and EOG electrodes (See Claim 1 and 15 Rejections). Nenov does not disclose, "the data from the monitoring device comprises at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a respiration, a blood velocity, an EEG, an ECG, and a body temperature". Attention is directed to the Williams et al. reference, which in a similar field of endeavor discloses the desirability of receiving EEG, ECG, and other data from a monitoring device (See Williams et al. column 2, lines 14-49). Therefore to aid in the treatment of brain injuries, it would have



been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Nenov to receive data from at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a respiration, a blood velocity, an EEG, an ECG, and a body temperature as taught by Williams et al. in order to more accurately assess the severity of a brain injury.

**In regards to Claim 32**, Nenov discloses a system using EMG and EOG electrodes (See Claim 21 Rejection). Nenov does not disclose “the monitoring device comprises at least one of a heart rate monitor, a pulse monitor, a blood pressure monitor, a carbon dioxide concentration sensor, a blood oxygen concentration sensor, a blood velocity sensor, an EEG monitor, an ECG monitor, and a body temperature sensor”. Attention is directed to the Williams et al. reference, which in a similar field of endeavor discloses the desirability of receiving EEG, ECG, and other data from a monitoring device (See Williams et al. column 2, lines 14-49). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Nenov to receive data from at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a respiration, a blood velocity, an EEG, an ECG, and a body temperature as taught by Williams et al. in order to more accurately assess the severity of a brain injury.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Bridger et al. (U.S. Patent 6887199).

**In regards to Claim 6**, Nenov disclose a method (See Claim 1 Rejection). Nenov does not disclose, “the brain injury protocol comprises one of an ischemic stroke and a

hemorrhagic stroke protocol". Attention is directed to the Bridger et al. reference, which in a similar field of endeavor discloses a brain assessment tool used to detect conditions such as head trauma, stroke, and hemorrhage (Bridger et al. column 3, lines 27-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a brain injury protocol for an ischemic stroke and/or a hemorrhagic stroke to the device of Nenov because such protocols would reduce the delay time in making a diagnosis of the type of brain injury, thus increasing the amount of time for therapeutic intervention.

8. Claims 7, 8, 13, 19, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Clifton (U.S. Patent No. 5486204).

**In regards to Claim 7**, Nenov discloses a method (See Claim 1 Rejection). Nenov does not disclose, "further comprising controlling a therapy device according to the brain injury protocol". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses controlling a therapy device according to a brain injury protocol (See Clifton column 3, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to have the device of Nenov control a therapy device according to the brain injury protocol because the protocol would encompass procedures for examining, evaluating and treating patients with actual or suspected brain injury, which would involve using a type of therapeutic device.

**In regards to Claim 8**, Nenov discloses a method (See Claim 1 Rejection). Nenov does not disclose, "the therapy device comprises one of a cooling device and a

drug delivery device". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses the use of a cooling blanket, a muscle relaxant and a sedative to treat brain trauma (See Clifton column 3, lines 24-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to include controlling a cooling therapy device or drug delivery device in the brain injury protocol of Nenov because creating a hypothermic environment for the patient is a method of treatment for brain injuries, which involves the use of cooling and drug delivery devices as taught by Clifton.

**In regards to Claim 13**, Nenov discloses a method (See Claim 12 Rejection). Nenov does not disclose, "further comprising controlling a therapy device as a function of the additional data". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses controlling a therapy device according to a brain injury protocol (See Clifton column 3, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to control a therapy device according to the brain injury protocol because the protocol would encompass procedures for examining, evaluating and treating patients with actual or suspected brain injury, which would involve using a type of therapeutic device.

**In regards to Claim 19**, Nenov discloses a method (See Claim 15 Rejection). Nenov does not disclose, "further comprising controlling a therapy device according to the brain injury protocol". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses controlling a therapy device according to a brain injury protocol (See Clifton column 3, lines 17-23). It would have been obvious to one of

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ordinary skill in the art at the time of the invention to control a therapy device according to the brain injury protocol because the protocol would encompass procedures for examining, evaluating and treating patients with actual or suspected brain injury, which would involve using a type of therapeutic device.

**In regards to Claim 22,** Nenov discloses a system (See Claim 21 Rejection).

Nenov does not disclose, "further comprising a therapy device to provide brain injury protocol as a function of the data". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses a therapy device to provide brain injury therapy (See Clifton column 3, lines 24-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide to the device of Nenov in light of the teaching of Clifton a therapy device to treat a brain injury because a therapy device is a tool used to improve the condition of a patient with a brain injury.

**In regards to Claim 25,** Nenov discloses a system (See Claim 22 Rejection).

Nenov does not disclose, "the therapy device comprises one of a cooling device and a drug delivery device". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses the use of a cooling blanket, a muscle relaxant and a sedative to treat brain trauma (See Clifton column 3, lines 24-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a cooling therapy device or drug delivery device in Nenov because creating a hypothermic environment for the patient is a method of treatment for brain injuries as taught by Clifton.

9. Claims 10, 11, 20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Zak et al (U.S. Patent Application Publication No. US2002/0004729).

**In regards to Claim 10,** Nenov discloses a method (See Claim 1 Rejection).

Nenov does not disclose “storing in an event log at least one of an action taken in the course of attending to the patient, a reception of the data from a monitoring device and a therapy delivered by a therapy device”. Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses storing patient treatment information in an event log (See Figure 9, element 400; also see Paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of the invention to store information in an event log in order to provide a medical treatment history that could be used to aid in the further treatment of the patient.

**In regards to Claim 11,** Nenov discloses a method (See Claim 10 Rejection).

Nenov does not disclose, “transmitting the event log to a remote unit” Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses transmitting patient data remotely (See Figure 1; also see Paragraph 55). It would have been obvious to one of ordinary skill in the art at the time of the invention to transmit the event log to a remote unit because providing information to a treatment facility in advance of the patient’s arrival reduces the delay in treating the patient.

**In regards to Claim 20,** Nenov discloses a method (See Claim 15 Rejection).

Nenov does not disclose “further comprising storing in an event log at least one of an action taken in the course of attending to the patient, a reception of the data from a

monitoring device and a therapy delivered by a therapy device". Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses transmitting patient data remotely (See Figure 9, element 400; also see Paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of the invention to store information in an event log in order to provide a medical treatment history that could be used to aid in the further treatment of the patient.

**In regards to Claim 36**, Nenov discloses a computer-readable medium (See Claim 33 Rejection). Nenov does not disclose "instructions causing the processor to store in an event log at least one of an action taken in the course of attending to the patient, a reception of the data from a monitoring device and a therapy delivered by a therapy device". Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses associating a procedure performed on a patient with a time stamp (See Paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a computer readable medium with instructions to compile information in an event log because providing a medical treatment history could be used to aid in the further treatment of the patient.

10. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Clifton (U.S. Patent No. 5486204) as applied to claim 22 above, and further in view of Klatz et al. (U.S. Patent No. 6277143).

**In regards to Claim 23**, Nenov in view of Clifton discloses a system (See Claim 22 Rejection). Nenov in view of Clifton does not disclose, "the processor is configured to control the therapy device as a function of the data". Attention is directed to the Klatz et

Art Unit: 3739

al. reference, which in a similar field of endeavor discloses a therapy device controlled by a microprocessor (See Klatz et al. column 11, line 57 – column 12, line 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a processor configured to control a therapy device as a function of the data because the processor would enhance the control of the therapy device through automating its control.

**In regards to Claim 24**, Nenov in view of Clifton discloses a system (See Claim 22 Rejection). Nenov in view of Clifton does not disclose, “the processor is configured to control the therapy device as a function of the brain injury protocol”. Attention is directed to the Klatz et al. reference, which in a similar field of endeavor discloses using a microprocessor to control a brain cooling apparatus (See Klatz et al. column 12, lines 6-9). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a processor configured to control a therapy device as a function of the brain injury protocol because the processor would enhance the control of the therapy device through automating its control.

11. Claims 35 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Klatz et al. (U.S. Patent No. 6277143).

**In regards to Claims 35 and 40**, Nenov discloses a computer-readable medium (See Claim 33 Rejection and Claim 38 Rejection). Nenov does not disclose “instructions causing the processor to control a therapy device according to the brain injury protocol”. Attention is directed to the Klatz et al. reference, which in a similar field of endeavor discloses using a microprocessor to control a brain cooling apparatus (See Klatz et al.

column 12, lines 6-9). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a computer-readable medium with instructions to control a therapy device according to the brain injury protocol because the medium provides an enhancement in the control of the therapy device by automating its controls.

***Response to Arguments***

12. Applicant's arguments filed November 28, 2005 have been fully considered but they are not persuasive.

*Claims 1-3, 5, 9, 12 and 14*

Applicant states, "Nenov does not suggest that the apparatus in any way selects a protocol, much less selects a brain injury protocol as a function of received data concerning a patient, as required by claim 1" and "Nenov fails to teach or suggest selecting a brain injury protocol as a function of data received from an operator concerning a patient, as required by claim 2." The Examiner directs the Applicant's attention to the specification, paragraph [0035], which states, "'brain injury protocol' also includes the instructions used by a processor such as microprocessor 18 to present information to assist an operator attending patient 10." Nenov Figures 4A and 4B show the decision tree used by the processor in the Nenov invention to provide the Glasgow Coma Score meeting the brain injury protocol definition mentioned above. Nenov discloses the use of checkboxes, pull-down menus and text fields to provide an operator with the ability to enter external factors that can alter the results of the invention (See Nenov column 17, lines 51-64). It is the Examiner's position that the Nenov invention meets the limitations of Claims 1-3, 5, 9, 12 and 14.



Claims 15-17

In regards to Claim 15, Nenov anticipates a checklist presented to an operator (See Nenov column 17, lines 51-64). From the specification, paragraph [0035] and clarified by the Applicant's remarks, an operator is described as an individual such as a nurse or doctor utilizing the device to aid a patient. Applicant is directed to the response to arguments for Claims 1-3, 5, 9, 12 and 14 to view the limitations of Claims 1 and 2 met by the Nenov invention. It is the Examiner's position that the Nenov invention meets the limitations of Claims 15-17.

Claims 21 and 26-31

In regards to Claim 21, Applicant is directed to the response to arguments for Claims 1-3, 5, 9, 12 and 14 and Claims 15-17 to view the limitations of Claims 1 and 15 met by the Nenov invention. It is the Examiner's position that the Nenov invention meets the limitations of Claims 21 and 26-31.

Claims 33, 34 and 37

In regards to Claim 33, Applicant is directed to the response to arguments for Claims 1-3, 5, 9, 12 and 14 to view the limitations of Claim 1 met by the Nenov invention. It is the Examiner's position that the Nenov invention meets the limitations of Claims 33, 34 and 37.

Claims 4, 6-8, 10, 11, 13, 18-20, 22-25, 32, 35, 36 and 40

Applicant states, "[The] applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention."

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, regarding Claim 6, Nenov and Bridger et al. are devices used in monitoring the neurological condition of a patient suffering some form of brain injury. Nenov specifically measures the level of consciousness utilizing electrodes and a microphone to monitoring eye, verbal and motor activity. Nenov also teaches the invention could be combined with an EEG device or a vital signs monitoring device (See Nenov column 18, line 36 – column 19, line 11). While, Bridger et al. measures brain impairment utilizing a brain sensor monitoring blood flow in the patient's brain to provide an early diagnosis of the cause of brain impairment. One of ordinary skill in the art from general knowledge would classify an ischemic or hemorrhagic stroke as a brain injury. Thus, combining devices to measure the level of consciousness and severity of brain impairment would be obvious to one of ordinary skill in the art. It is the Examiner's position that the Nenov in view of Bridger et al. invention meets the limitations of Claim 6.

Regarding Claims 7, 19 and 22, Clifton utilizes the Glasgow Coma Scale as part of the criteria in classifying patients capable of having the invention administered to

them (See Clifton column 3, lines 44-63). The Nenov invention provides an operator with checkboxes, pull-down menus and text fields to provide an operator with the ability to enter external factors that can alter the results of the invention (column 17, lines 51-64). Nenov provides examples of these external factors, such as pharmacological drug use. Thus, Nenov is teaching the invention could be combined with some type of drug therapy. It is the Examiner's position that the Nenov in view of Clifton invention meets the limitations of Claims 7, 8, 13, 19, 22 and 25.

### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth C. Williams whose telephone number is (571) 272-8161. The examiner can normally be reached on Monday-Friday.

Art Unit: 3739

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCW

A handwritten signature in black ink, appearing to be 'LD' with a large loop, positioned above the printed name.

LINDA C. M. DVORAK  
SUPERVISORY PATENT EXAMINER  
GROUP 3700